Coverage Analysis

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What is Coverage Analysis?

Coverage Analysis (CA) is a financial review of a Clinical Research Study that is required to be performed pursuant to the Federal Clinical Trials Policy (also known as the National Coverage Decision (NCD310.1)). In brief, Coverage Analysis is a three-step process (additional info below) that evaluates whether a study meets the Federal definition of a Qualifying Clinical Trial (QCT), and evaluates whether certain study-related services may be considered Routine Costs billable to patients and/or their insurers under Federal law. A Coverage Analysis is often associated with development of a billing grid, a tool which facilitates compliant clinical research billing, that distinguishes financial responsibility for study-related services between study funding and patients/insurers. UCLA Policy 915 requires Coverage Analysis be performed for any clinical research study requiring UCLA Health System resources, including but not limited to any patient care costs.

Coverage Analysis Review Objectives

1. Identify and document whether a study is a Qualifying Clinical Trial (QCT), as defined by Federal law, that may support billing certain study required items/services to insurance pursuant to applicable laws and regulations; and
2. Determine and document financial responsibility for all patient care costs required by the study. Financial responsibility for study required items/services may either be:
    - Routine Costs that may be billed to a study participant and/or their insurer(s); or
    - Study Costs for items/services that are primarily required for research purposes and should be paid for by research funding and/or support.
3. Evaluate Medicare Coverage (via National and/or Local Coverage Determinations), and document support for items/services considered Routine Costs billable to patients/insurers.

How Routine Costs are Determined

The Centers for Medicare & Medicaid Services (CMS) provide guidance to help differentiate Routine Costs from Study Costs. National and Local Coverage Determinations, professional medical association guidance, commercial drug compendia, and nationally recognized peer-reviewed publications are often utilized as resources to support Coverage Analysis billing designations.

Coverage Analysis & Financial Activation Fees

Study	Applicable Fee effective 3/1/25
Non-Profit Funded Studies (including NIH)	N/A
Industry-Sponsored Studies	$2,950
Industry-Sponsored Budget Amendments (per occurrence)	$1,250

Coverage Analysis and Financial Activation and amendment fees include the administrative cost of evaluating the QCT status for clinical research studies and development and protocol-driven updates of a compliant billing grid in the UCLA Clinical Research Management System. Fees listed above represent the direct cost of the associated service and are subject to the applicable UCLA indirect rate.

For additional information and/or questions, please email CoverageAnalysis@mednet.ucla.edu. Please see Related Guidance for further information.

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UCLA Clinical Research Pricing Overview

UCLA Policy 915.1 (Pricing for Budgeting and Contracting of Clinical Research Studies) is intended to provide transparency, consistency, and facilitate compliance with applicable research finance regulatory requirements. UCLA Policy 915.1 defines the key criteria and application of standardized research rates for clinical research studies facilitated across the UCLA enterprise and informs the UCLA Clinical Research Chargemaster and subsequent updates and iterations.

UCLA Clinical Research Chargemaster Goals

- **Transparency**: Clear methodology and consistent pricing.
- **Efficiency**: Streamline budgeting & applicable negotiation.
- **Compliance**: Adherence to regulatory and institutional policies and procedures.

For-Profit and Non-Profit Research Rates

UCLA's Clinical Research Chargemaster establishes two distinct rate bases, for-profit research rates and non-profit research rates, which are set based on the source of funding/support for a clinical research study.

- **For-Profit Supported Study** is a Clinical Research Study that is funded extramurally by a for-profit organization.
- **Non-Profit Supported Study** is a Clinical Study that is funded extramurally by a governmental or non-profit organization, or internally funded through departmental/division funds, and/or other discretionary funds utilized by the Principal Investigator (PI) (including but not limited to PI and staff time and effort used to conduct the Clinical Study).

Chargemaster Items & Services

The UCLA Clinical Research Chargemaster includes Procedural Research Costs as well as standard Administrative Research Costs, as defined below:

Procedural Research Cost(s) is any procedure, service or item, including but not limited to those procedures, services and / or items identified by: Current Procedural Terminology (CPT), Diagnosis- Related Group (DRG), Ambulatory Payment Classifications (APC), and International Classification of Diseases (ICD) codes required by a Clinical Study that can, though not necessarily will, be charged to a patient or third party payer (e.g. CMS, medical insurance providers, etc.) by either the hospital or faculty practice billing groups.

Administrative Research Cost(s) are item(s)/service(s) that are not Procedural Research Cost(s) but may be required to activate, coordinate, maintain, amend, and/or closeout a clinical research study across the UCLA enterprise.

UCLA Clinical Research Chargemaster Access

UCLA's Annual Research Charge Masters are available online and to UCLA AD account holders on UCLA intranet or via UCLA VPN access at the following link: http://finance.mednet.ucla.edu/cdmweb/clinicaltrial/default.htm

For questions related to the UCLA Clinical Research Chargemaster, please contact the UCLA Charge Description Master (CDM) Research Team at CDMResearch@mednet.ucla.edu.

UCLA Standard Administrative Clinical Research Fees

UCLA's standard administrative clinical research fees are available online at the following link: https://www.researchgo.ucla.edu/ucla-standard-administrative-clinical-research-fees

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Coverage Analysis at UCLA Health System

Coverage Analysis at UCLA is performed centrally by the Clinical Research Finance team within the Dean's Office School of Medicine and Clinical and Translational Science Institute (CTSI).

How is Coverage Analysis Initiated?

Coverage Analysis is integrated in the ResearchConnect study activation and budget development process at UCLA. **When a new clinical research study application is submitted in the UCLA BruinIRB system, the Clinical Research Finance team is automatically notified to begin the Coverage Analysis and budget development process.**

Financial Coverage & Activation Process

Once the Clinical Research Finance team receives an automatic notification that a new clinical research study has been submitted in the UCLA web-IRB system, the Clinical Research Finance team will transfer the Core Study Documents (draft informed consent, protocol, investigator brochure and device manual if applicable) from the UCLA BruinIRB system into the OnCore Clinical Research Management System, and begin the Financial Coverage & Activation Process by performing the following tasks:

1. Evaluate whether any UCLA Health System resources are required;
2. Evaluate whether any core ancillary department services are required (e.g. Laboratory/Pathology, Radiology, Investigational Pharmacy and/or Industry Clinical Trial Contracting) and trigger automatic notifications to ancillaries and study teams, as applicable;
3. Evaluate whether study required items/services will be: (1) all billed to the study sponsor and/or internal study account; or (2) all billed to the participant and/or their insurer(s); or (3) a mix of patient/insurance costs and study costs.

For additional information and/or questions, please email CoverageAnalysis@mednet.ucla.edu. Please see Related Guidance for more information.

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Device study Coverage Requirements

Investigators participating in an Investigational Device Exemption (IDE) Study that plans to request reimbursement for study procedures and materials from Medicare or third-party payers must ensure the following:

1. CMS IDE study coverage has been approved by CMS or local Medicare contractor
    - CMS approval of coverage for Category A devices applies to the routine care items and services required by the study, but not the experimental device
    - CMS approval of coverage for Category B devices allows for coverage of the routine care items and services required by the study as well as the investigational device.
2. Other devices that may be covered by Medicare include
    1. Premarket Approval (PMA)
    2. Humanitarian Device Exemption (HDE)
    3. 510(k) approved devices
    4. IRB-approved Non-Significant Risk (NSR) devices
3. UCLA Value Analysis Committee (VAC) approval has been granted – If the study requires UCLA to purchase or use a new or replacement technology/device, then a VAC Request Form must be submitted for review

Drugs Study Coverage Requirements

Medicare will cover the cost of QCTs that are conducted under an Investigation New Drug (IND) reviewed by the FDA. IND exempt studies are deemed automatically qualified for coverage until further qualifying criteria are available. Once the qualifying criteria are available, the Principal Investigators of the study must certify that the study meets all qualifying criteria for Medicare coverage of routine costs. The new qualification will apply to the prospective study charges generated.

Please see Related Guidance for more information.

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